REMARKS

Claims 1, 6-7, 9-30, 32, 34-35, 37-38, and 40 are pending. Claims 17, 21-28, 32, 34-35, 37-38, and 40 are withdrawn from consideration and canceled herein without prejudice. Claims 1, 6-7, 9-16, 18-19, and 29 are amended herein to clarify the subject matter recited therein. New claims 41-42 are submitted herewith. Accordingly, instant claims 1, 6-7, 9-16, 18-20, 29-30, and 41-42 are presently under consideration.

Support for amendment to the claims is found throughout the specification and in the original claims. More particularly, support for amendment to claim 1 is presented, for example, in original claim 11 and at page 7, line 26 through to page 8, line 2; page 31, lines 1-3; and in Figure 4. Support for amendment to claims 13 and 14 is found, for example, at page 9, lines 9-30; and page 31, lines 1-22; and in Figure 5. Support for amendment to claims 1, 6-7, 9-16, 18-19, and 29 is also found at page 6, lines 3-5. No issue of new matter is introduced by the amendments to the claims.

Support for new claims 41 and 42 is found throughout the specification and in the original claims. More particularly, support for new claims 41 and 42 is presented, for example, in original claims 1, 11, and 13 and at page 9, lines 9-30; and page 31, lines 1-22; and in Figure 5. No issue of new matter is introduced by the amendments to the claims.

Specification

The specification is objected to for the presence of informalities. The specification has been reviewed to identify use therein of trademarks. It is believed that the specification is amended to refer properly to trademarks cited therein. The specification is also hereby amended to delete reference to embedded hyperlinks and/or other forms of browser-executable code. The arrangement of the specification has also been amended to include appropriate section headings and to arrange such section headings in order in accordance with the Examiner's request. In light of the above, it is believed that these objections have been addressed and the Examiner is respectfully requested to withdraw the objections to the specification. No issue of new matter is hereby introduced.

Sequence Compliance

The specification is amended herein to include sequence identifiers for nucleic and amino acid sequences referred to therein. A Substitute Sequence Listing is forwarded herewith that includes these sequences. No issue of new matter is hereby introduced.

Drawings

The drawings are objected to because Figures 7a and 10 are viewed as dark, thus rendering the images difficult to discern. Replacement Drawings for Figure 7a-b and 10 are forwarded herewith. It is, therefore, believed that the instant drawings are discernable and Applicant respectfully requests that the objection be withdrawn. No issue of new matter is hereby introduced.

Claim Objections

Claims 10-11 and 13 are objected to as dependent upon a rejected base claim. In view of the amendments to the claims, Applicant believes that the objections are addressed herein and may be withdrawn.

Rejection Under 35 U.S.C. § 101

Claims 1, 6-7, 9, 13-16, 18-20, and 29-30 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. In accordance with the Examiner's suggestion, claims 1, 6-7, 9-16, 18-19, and 29 are amended herein to recite "isolated". In view of the clarifying amendments to the claims, the rejection as it applied to claims 1, 6-7, 9, 13-16, 18-20, and 29-30 is respectfully traversed.

Rejections under 35 USC § 112

Claims 1, 6-7, 9-10, 13-16, 18-20, and 29-30 are rejected under 35 USC § 112, first paragraph, for containing subject matter which is allegedly not described in the specification in

such a way as to convey that the inventor was in possession of the claimed invention at the time of filing. In view of the amendments to the claims and Applicant's arguments presented herein, the rejection, as it applied to claims 1, 6-7, 9-10, 13-16, 18-20, and 29-30, is respectfully traversed.

Claim 1 is amended to be directed to an isolated complement inhibitor polypeptide derived from a haematophagous arthropod that inhibits the classical complement pathway and the alternative complement pathway by inhibiting cleavage of C5 by classical and alternative C5 convertases, wherein the isolated complement inhibitor polypeptide is a protein having at least 90% identity to a protein comprising amino acids 19 to 168 of the amino acid sequence of SEQ ID NO: 2. Claims 13 and 14 are amended, *inter alia*, to be directed to an isolated complement inhibitor polypeptide that inhibits the classical and alternative complement pathways (claim 13) or that inhibits cleavage of C5 by a C5 convertase (claim 14), wherein said complement inhibitor is: a protein comprising amino acids 19 to 168 or amino acids 1 to 168 of the amino acid sequence of SEQ ID NO: 2; a homologue of a protein as defined in a) having at least 95% identity thereto; or an active fragment of said protein as defined in a) above, wherein said active fragment comprises six cysteine residues that are spaced relative to each other at a distance of 32 amino acids apart, 62 amino acids apart, 28 amino acids apart, 1 amino acid apart, and 21 amino acids apart as arranged from the amino terminus to the carboxyl terminus, wherein said active fragment inhibits cleavage of C5 by classical and alternative C5 convertases. Accordingly, the instant claims are amended herein to clarify both functional and structural properties of the claimed isolated complement inhibitor polypeptides.

More particularly, the instant claims are directed to isolated complement inhibitor polypeptides that have at least 90% identity to a protein comprising amino acids 19 to 168 of the amino acid sequence of SEQ ID NO: 2 or to active fragments that include the six cysteine residues of SEQ ID NO: 2, all of which are located relative to each other in precisely the positional arrangement found in SEQ ID NO: 2. With regard to a polypeptide having 90% identity to a protein comprising amino acids 19 to 168 of the amino acid sequence of SEQ ID NO: 2, the specification teaches the amino acid sequence of SEQ ID NO: 2 and how to

determine various degrees of percent identity. See, for example, Figure 4 and page 7, line 26 through to page 8, line 2. With regard to active fragments of SEQ ID NO: 2, the specification teaches that the juxtaposition of the cysteine residues of SEQ ID NO: 2 is structurally significant and confers on a polypeptide including this arrangement of cysteines a disulfide bridging pattern that is predictive of overall protein structure. See, for example, page 31, lines 1-22 and Figure 5. Moreover, the specification teaches that the primary sequence of OmCI shows 58% identity to tick Salivary Gland Proteins 2 and 3 (TSGP2 and 3) of the soft tick Ornithodorus savigny and 49% identity to moubatin from Ornithodorus moubata. See, for example, page 31, lines 11-15 and Figure 5. Figure 5 also shows the identities and positions of the amino acids that are identical with respect to the three most related polypeptides (OmCI, TSGP2, and TSGP3) depicted therein. An ordinarily skilled practitioner would also be able to identify related amino acids (e.g., acidic amino acids or basic amino acids) that align positionally among these three highly related proteins based on the alignment of Figure 5. The presence of conservative amino acid substitutions at a particular position identified based on such an alignment, such as, for example, the presence of glutamic acid in OmCI and the presence of aspartic acid in TSGP2 or TSGP3 would also be instructive to an ordinarily skilled practitioner.

In light of the extensive written description presented in the specification pertaining to the amino acid sequences of these highly related proteins and the identification of amino acids at positions that are identical or related (wherein conservative amino acid substitutions are found) among the three most related polypeptides (OmCI, TSGP2, and TSGP3), an ordinarily skilled practitioner would be able to envision the claimed polypeptides. That being the case, Applicant asserts that sufficient written description is presented in the specification to demonstrate to one of ordinary skill in the art that the inventor was in possession of the claimed invention at the time of filing.

Thus, in light of the amendments to the claims and support presented in the specification, Applicant maintains that the instant claims are sufficiently described by the specification. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 6-7, 9-10, 13-16, 18-20, and 29-30 under 35 U.S.C. § 112, first paragraph, for allegedly

failing to comply with the written description requirement.

For the record and contrary to the Examiner's assertions, the claimed genus of polypeptides does not include non-functional proteins. See comments spanning pages 9-10 of the Office Action. The functional attributes of the claimed genus of polypeptides were and are recited in the claims. The Examiner is respectfully requested to acknowledge this distinction.

Claims 1, 6-7, 9-10, 13-16, 18-20, and 29-30 are rejected under 35 USC § 112, first paragraph, for containing subject matter which is allegedly not enabled by the specification. In view of the amendments to the claims and Applicant's arguments presented herein, the rejection, as it applied to claims 1, 6-7, 9-10, 13-16, 18-20, and 29-30 is traversed.

As detailed above, the claims are amended to clarify both functional and structural properties of the claimed isolated complement inhibitor polypeptides. Applicant's arguments as presented herein above with regard to satisfying the written description requirement are, moreover, incorporated herein in their entirety. Accordingly, Applicant asserts that the instant specification presents guidance pertaining to the structure of the claimed polypeptides. See, for example, page 31, lines 1-22 and Figure 5. In addition to the information presented in the specification, an ordinarily skilled practitioner would also be aware of the scientific literature relating to the structural configuration of lipocalin beta barrel proteins and more specifically, to the structural configuration of the histamine binding protein family of tick specific proteins, of which SEQ ID NO: 2 (OmCI) is a member. With the above in mind, an ordinarily skilled practitioner possesses substantial information on which basis to predict which amino acids within SEQ ID NO: 2 can be altered while still maintaining the claimed function. Moreover, the high degree of recited identity required for polypeptide homologues encompassed by the instant claims, in combination with the conserved overall structure maintained by disulfide bridging between the conserved cysteines as recited for the active fragments, narrows the genus of encompassed polypeptides considerably. That being the case, an ordinarily skilled practitioner would not view the instant claims as encompassing an infinite number of variants/fragments as suggested in the Office Action. The specification also teaches how to test polypeptide homologues and active fragments in accordance with the present invention. See, *inter alia*, the

Examples spanning pages 23, line14 through to page 32, line 30 for details. In view of the above, Applicant asserts that sufficient guidance is presented in the specification to instruct an ordinarily skilled artisan to practice the invention. Given the high degree of identity and conserved sequences required and the structural particulars conferred thereby as recited with respect to the claimed polypeptides, testing the genus of claimed variants of SEQ ID NO: 2 and fragments of SEQ ID NO: 2 would not require undue experimentation.

With regard to the Examiner's apparent reliance on Seffernick et al. (J. Bacteriology 183:2405-2410, 2001) in support of the high degree of unpredictability in the field, Applicant responds that there are numerous examples of polypeptides whose function is preserved even after mutation of one or more amino acids therein. Applicant, therefore, reserves the right to submit references in support of this assertion at a later stage of prosecution should this be necessary for advancement of the claims to allowance. The Examiner's comments pertaining to Wells (Biochemistry 29:8509-8517, 1990) are also duly noted. Applicant reserves the right to address issues raised in connection with this reference at a later date in prosecution, should the Examiner view the Wells reference as having any relevance to the instant claims following consideration of arguments presented herein.

In light of the clarifying amendments to the claims and arguments presented herein, Applicant asserts that the instant claims are enabled by the specification. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of the claims under 35 USC § 112, first paragraph.

Rejections under 35 USC § 102

Claims 1 and 6-7 are rejected under 35 USC § 102(b) as allegedly anticipated by Ashgar et al. (Molecular Immunology 23:459-465, 1986). Claim 1 is amended herein to clarify the claimed subject matter. In view of the amendments to the claims and arguments presented herein, the rejection, as it applied to claims 1 and 6-7, is respectfully traversed.

As indicated above, claim 1 is amended to be directed to an isolated complement inhibitor polypeptide derived from a haematophagous arthropod that inhibits the classical

complement pathway and the alternative complement pathway by inhibiting cleavage of C5 by classical and alternative C5 convertases, wherein the isolated complement inhibitor polypeptide is a protein having at least 90% identity to a protein comprising amino acids 19 to 168 of the amino acid sequence of SEQ ID NO: 2. It is, therefore, apparent that Ashgar et al. fails to teach several recited elements of the instant claims. At the outset, the Ashgar et al. reference discloses only chemical inhibitors of the alternative and classical complement pathways and fails to teach or suggest that inhibitors of these pathways could be derived from any natural source, including haematophagous arthropods. Indeed, the reference is silent with regard to any potential for the existence of complement inhibitor polypeptides having the claimed properties in nature. The Ashgar et al. reference also, moreover, fails to teach or suggest the isolated complement inhibitor polypeptides as claimed.

In light of the amendment to the claims and the deficiencies of Ashgar et al. with respect to the instant claims, Applicant respectfully requests that the rejection of claims 1 and 6-7 under 35 USC § 102(b) in view of this reference be withdrawn.

Fees

No additional fees are believed to be necessitated by this amendment. However, should this be an error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overpayment.

Conclusion

It is submitted, therefore, that the claims are in condition for allowance. No new matter has been introduced. From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited. In the event that there are any questions concerning this amendment, or application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,

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Dated: September 14, 2009

Enclosures: Petition for Two Extension of Time
Substitute Sequence Listing, Amendment directing entry of same, and Statement in Support thereof
Replacement Drawings for Figure 7a-b and 10